ROUTING AND RECORD SHEET

SUBJECT: (Optional)

25X1 Proposed Revision of [redacted] Restrictions on Intelligence Activities (Job #9420)

FROM:	EXTENSION	NO.
Don I. Wortman 25X1 Deputy Director for Administration 7D24 Hqs.		OIS 81-027 DATE 14 JAN 1981

DD/A Registry
81-0086

TO: (Officer designation, room number, and building)	DATE RECEIVED	DATE FORWARDED	OFFICER'S INITIALS	COMMENTS (Number each comment to show from whom to whom. Draw a line across column after each comment.)
1. DDCI				The attached proposed revision of [redacted] is forwarded for approval. The proposal has the concurrence of all members of an Agency task force established to study biomedical and behavioral research. The Agency Task Force consisted of Dr. [redacted] as chairman and representatives from OGC, IG, NFAC, DDO, and DDS&T. OGC has formally concurred on this proposed revision. DD/A REGISTRY FILE: O+M-1
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FORM 1-79 610 USE PREVIOUS EDITIONS

HQ. INSTRUCTION SHEET

25X1

REMOVE			INSERT			EXPLANATION
REG. NOS.	PAGE NOS.	DATE	REG. NOS.	PAGE NOS.	DATE	
[redacted]	3 7	9/15/78 9/15/78				[redacted] is revised to define the Institutional Review Board and research on human subjects. Paragraph c(1)(k) is expanded to establish and define the functions of the Human Subject Research Panel. Paragraph c(1)(k) is also revised to reflect the redesignation of the Department of Health, Education and Welfare as the Department of Health and Human Services.

Arrows in the page margin show the locations of the changes described above.

25X1

DISTRIBUTION: AB

16 JAN 1981

MANAGEMENT

25X1

1. RESTRICTIONS ON INTELLIGENCE ACTIVITIES

SYNOPSIS. No change.

a. GENERAL. No change.

b. DEFINITIONS. For the purpose of this regulation, and except as may be provided in the annexes to this regulation, the following terms shall have these meanings:

(1) through (12) No change.

(13) ''Institutional Review Board'' means a panel, created in accordance with the requirements of 45 CFR 46 by an institution (external contractor or Agency component) conducting research on human subjects, responsible for determining whether human research subjects will be placed at risk and, if risk is involved, whether (a) the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks, (b) the rights and welfare of any such subject will be adequately protected, and (c) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of 45 CFR 46.

(14) ''Research on human subjects'' means a formal investigation, designed to develop or contribute to generalizable knowledge, the subjects of which are persons about whom a scientist conducting research obtains data through intervention or interaction with the person or identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulation of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the research scientist and the subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to fall within this definition. Data collection and analysis conducted within the limits of the normal course of approved administrative, analytical, or operational activities does not constitute research under this definition.

c. POLICY

(1) RESTRICTIONS ON COLLECTION

(a) through (j) No change.

(k) Restrictions on Experimentation. No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines.

(1) The Director, through an Agency Human Subject Research Panel (HSRP), hereby established, shall evaluate all documentation and certification pertaining to human research sponsored by, contracted for, or conducted by the CIA (including initial and ongoing reviews conducted by Institutional Review Boards) prepared in compliance with Department of Health and Human Services guidelines, codified at 45 CFR 46. The HSRP shall be composed of such offices and employees of the CIA and such experts or consultants engaged for this purpose as the Director determines to be appropriate.

(2) On the basis of his evaluation of documentation submitted in accordance with the requirements of this regulation, the Director shall approve, require such modifications to submissions as to make them acceptable, or disapprove. With respect to approved documentation, the Director may determine the period during which approvals remain effective or otherwise condition or restrict his approval.

(3) The Agency HSRP shall disseminate procedural instructions and information necessary for the establishment and operation of Institutional Review Boards within the Agency as required by 45 CFR 46. The HSRP shall provide material to assist the components to comply with [redacted] 25X and shall standardize information necessary for documentation and certification as required by 45 CFR 46 of institutions conducting research on human subjects.

No further changes.

/s/ Frank C. Carlucci

Frank C. Carlucci
Deputy Director of Central Intelligence

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25X1 RCD [redacted] (12 Jan 81)

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